

Message

From: McAllister, Janet (CDC/OID/NCEZID) [jvm6@cdc.gov]
Sent: 12/14/2016 6:56:30 PM
To: Evdokimov, Evgenij A (FDA/CVM) [Evgenij.Evdokimov@fda.hhs.gov]; Wozniak, Chris [wozniak.chris@epa.gov]
CC: Dass, Brinda (FDA/CVM) [Brinda.Dass@fda.hhs.gov]
Subject: RE: Oxitec update

Evgenij,
Thank you for the update.

Janet McAllister, PhD, BCE

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From: Evdokimov, Evgenij A (FDA/CVM)
Sent: Wednesday, December 14, 2016 7:09 AM
To: Wozniak, Chris (wozniak.chris@epa.gov) (wozniak.chris@epa.gov) <wozniak.chris@epa.gov>; McAllister, Janet (CDC/OID/NCEZID) <jvm6@cdc.gov>
Cc: Dass, Brinda (FDA/CVM) <Brinda.Dass@fda.hhs.gov>
Subject: Oxitec update

Dear colleagues,

I just wanted to give you an update on the latest developments with Oxitec. Recently, Oxitec proposed to conduct an investigational study or studies in one or more other locations of Monroe County, FL. In support of this proposal, the sponsor submitted an EA for investigational use of OX513A mosquitoes for all of Monroe County, FL. CVM's preliminary review established that the sponsor's EA does not include relevant information about Monroe County, FL. Examples of missing information include but are not limited to potential sources of tetracycline in the environment, (e.g., presence of hospitals, waste water treatment facilities, farms, etc.), information on all Monroe County national parks/national wildlife refuges and endangered species and how they might be impacted by the proposed trial and trial site location(s), and ranges of numbers of Oxitec male mosquitoes that potentially would be released at the trial site(s), including how those numbers affect the number of females that could be released and how those numbers affect the assessment of potential risk to humans and other animals including that related to bites. The Monroe County EA is also missing other site-specific information comparable to the site-specific information included in FDA's final Key Haven EA. Therefore, we concluded that their submission is incomplete and we requested that the sponsor provides necessary information in their re-submission.

Please let Brinda or me know if you have any additional questions.

Thank you,

Evgenij

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